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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,861 02/11/00 RICCARDI

C RICCARDI=1

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624 NINTH STREET  
WASHINGTON DC 20004

HM12/0621

EXAMINER

EPFS.J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

06/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/403,861

Applicant(s)

RICCARDI, CARLO

Examiner

Janet L. Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14,24,26-30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-14,24,26-30,32-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to DNA which encodes a GILR protein, DNA vector, and host cells.

Group II, claim(s) 11-12 and 26, drawn to protein and pharmaceutical composition comprising said protein.

Group III, claim(s) 13, drawn to a recombinant method of making a protein.

Group IV, claim(s) 14 and 35, drawn to an antibody and method of using said antibody.

Group V, claim(s) 24, screening process for isolating and identifying proteins according to claim 11 which are GILR-like proteins belonging to the leucine zipper family or are proteins capable of binding directly to GILR.

Group VI, claim(s) 27, drawn to pharmaceutical composition comprising a recombinant animal virus encoding a protein capable of binding a cell surface receptor and encoding at least one GILR protein or derivative.

Group VII, claim(s) 28, drawn to antisense pharmaceutical composition.

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Group VIII, claim(s) 29, drawn to a pharmaceutical composition comprising an inactive mutant GILR protein of DNA sequence encoding said inactive mutant GILR protein, which GILR mutant.

Group IX, claim(s) 30 and 40, drawn to a pharmaceutical composition comprising a peptide inhibitor capable of binding to the active site or the leucine zipper domain of GILR and a method of using said peptide inhibitor.

Group X, claim(s) 32-34, drawn to methods of inhibiting, in cells, apoptosis mediated by the Fas/FasL system, CD3/TCR system.

Group XI, claim(s) 36-37, drawn to a method of enhancing apoptosis in cells by inhibiting the activity of GILR proteins in said cells comprising treating said cells with an oligonucleotide sequence encoding an antisense sequence for at least part of the DNA sequence encoding a GILR protein.

Group XII, claim(s) 38, drawn to a method of enhancing apoptosis for treating tumor cells, HIV-infected cells, or other diseased cells comprising infecting said tumor with a recombinant animal virus vector carrying a sequence encoding a viral surface protein capable of binding to a specific tumor cell surface receptor of HIV-infected cell surface receptor and a sequence encoding an inactive GILR mutant protein.

Group XIII, claim(s) 39, drawn to a method of enhancing apoptosis in cells comprising a ribozyme procedure.

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2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: It appears that the linking technical feature shared between Groups I-XIII is the glucocorticoid-induced leucine zipper family related protein (GILR) or the DNA sequence encoding said protein. However, the instant claims read on a DNA sequence comprising at least part of the DNA sequence SEQ ID NO:1, 2, or 5 and encoding at least one active human GILR protein. The prior art clearly discloses that members of the GILR family of leucine zipper protein share a high degree of sequence homology between members of the protein family. Shibanuman et al., Jay et al., and Barrett et al. disclose proteins sharing at least part of the DNA sequence of SEQ ID NO:1, 2, or 4, and further encoding a leucine zipper family related protein. It is also noted that applicants do not clearly define the intended meaning of the term "comprising at least part of" with regards to SEQ ID NO:1, 2, or 4. Since the special technical feature of Groups I-XIII has been found in the art, a technical relationship does not exist between the claimed Groups. Therefore, unity of invention is lacking.

3. Additionally, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under *PCT Rule 13.1* which states: The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). See also *PCT Rule 13.2* states:

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Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution that each of the claimed inventions, considered as a whole, makes over the prior art.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L Epps  
Examiner  
Art Unit 1635

jle  
June 19, 2001